

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS - FORT WORTH DIVISION

JAMES SHEPHERD, et al., §
§ CIVIL CAUSE NO.
v. § 4:23-cv-826
§
ENVIRONMENTAL PROTECTION AGENCY, et al., §
Defendants. §

PLAINTIFFS' REPLY IN SUPPORT OF
APPLICATION FOR PRELIMINARY INJUNCTION AGAINST THE
ENVIRONMENTAL PROTECTION AGENCY

Plaintiffs herein reply to the EPA's *Memorandum in Support of Response in Opposition to Plaintiffs' Motion for Preliminary Injunction* ("Memorandum"). Plaintiffs incorporate their *Amended Complaint*, concurrently filed, which amends the claims for clarity and adds the JBS Trust as a Plaintiff, as well as additional facts in support of standing. Plaintiffs' *First Amended Complaint* is filed simultaneously with this reply and should be relied on for Plaintiffs' claims moving forward. Plaintiffs assert that the underlying reasons for granting the injunction are unchanged; the real difference between the Original and First Amended Complaints is the added plaintiff and details to clarify standing. The Court should continue with the injunction process.

To summarize, Defendant argues that 1) Plaintiffs lack standing; and 2) Plaintiffs cannot succeed on the merits. First, Plaintiffs herein rebut Defendant's arguments in part by adding the JBS Trust as a plaintiff and showing how the SSUROs have damaged royalty payments and vendor arrangements. Second, Plaintiffs defend the merits of their claims, showing that the EPA ignores the lack of pesticidal intent in Berkey filters, and the absence of pesticidal uses of silver in a pesticidal claim by Plaintiffs or SSURO recipients. Plaintiffs show that Berkey's filters are treated articles, not pesticides. Even the EPA's Appendix shows that Berkey filters are mechanical, making no non-mechanical pesticide purpose claims. The EPA has acted arbitrarily and capriciously without due process and in clear error of judgment.

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I. ARGUMENTS

1. In this case, Plaintiffs have standing and their filters are not a pesticide. Plaintiffs JBS Trust is entitled to royalty payments which have been impacted by the SSUROs, which prevent sale of Berkey filters. NMCL has standing because its vendor, Berkey Int'l has been shut down. The James B. Shepherd Trust has been added as a Plaintiff in Plaintiffs' First Amended Complaint, filed contemporaneously with this Reply, to add additional support for standing based on lost royalties.
2. The EPA cannot explain how Berkey filters are a pesticide, rather than a pesticide device or treated article. The EPA cannot claim that silver makes the filters a pesticide when the silver is part of a registered pesticide applied to the filters to protect the filters, and not for pesticidal effect on the filtered water. The EPA's actions are indefensible.

A. Plaintiffs have Article III standing.

3. To establish standing, a plaintiff must show that he or she suffered an injury that is (1) "concrete, particularized, and actual or imminent"; (2) "fairly trace[able] to the challenged action, and not . . . th[e] result [of] the independent action of some third party not before the court"; and (3) "it must be likely as opposed to merely speculative that the injury will be redressed by a favorable decision." *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560 (1992).
4. Plaintiffs have standing just as franchisor Pizza Hut did when its franchisees' royalty payments and franchise relationship was impacted in *Pizza Hut, LLC v. Ronak Foods, LLC*, Franchisee Defendants allege that IPHFHA is not a party to this suit and therefore Pizza Hut has no damages or standing as to the Advertising Fees. However, the Court determines otherwise, based on the aforementioned crediting operation in the Franchise Agreement. If a Franchisee Defendant fails to pay any of the fees it owes to IPHFHA, then that Franchisee Defendant would not get a credit to offset its payment obligations to Pizza Hut—and then Pizza Hut would be owed the amount due.

5:21-CV-00089-RWS, 2022 WL 3544403, at *11-12 (E.D. Tex. June 17, 2022), aff'd sub nom.

Pizza Hut L.L.C. v. Pandya, 22-40555, 2023 WL 5359079 (5th Cir. Aug. 22, 2023).

5. Just as in *Pizza Hut, LLC v. Ronak Foods, LLC*, this case presents a licensor entitled to license payments through a percentage of gross sales and royalty payments. *Id.* The decision allowed standing for the licensor to sue according to such payments, and was upheld by the 5th Circuit as indicated. As explained in both the Second Declaration of Jim Shepard and in more detail in the concurrently filed Declaration of James “Jim” B Shephard Regarding Trade Secrets (First Amended Complaint, Exhibit E, filed separately under seal), JBS Trust is losing royalties owed on gross sales of Berkey International and NCML, which have stopped due to the SSUROs, and NCML has lost its major vendor and cannot obtain product to sell.

6. Based on the above, Plaintiffs have Article III standing:

1) JBS Trust and NMCL have been damaged due to lost royalties and lost sales, because the SSUROs stop sales and resulting royalties. Every day the SSUROs are active takes sales away that would normally contribute to the payments from NMCL and Berkey Int’l to the JBS Trust in the regular course of business. Exh. A, B, D, & E. *See id; Lujan*, 504 U.S. at 560.

2) SSUROs require the recipients to stop selling certain specified products. The EPA has shut down Berkey International, LLC and many others that have similar agreements with JBS Trust, or have agreements with NMCL or Berkey International, LLC. At the very least, SSUROs have stopped Berkey International, LLC’s sales, significantly harming its royalties based on gross sales, as well as royalty payment for sales protected by the IP from Berkey International, LLC and NMCL. Exh. A, B, D, & E. *See Id.*

3) This court can redress the injury with a favorable decision by declaring the EPA’s SSUROs as arbitrary, capricious, an abuse of discretion, and in clear error of judgment, and by issuing an injunction against the EPA or EPA agents named in this case from enforcing the SSUROs against Berkey Products. This court can redress the injury by declaring Berkey Products to be a pesticide device or a treated article or declaring them to be outside the regulatory

jurisdictions of FIFRA entirely. This court could redress Plaintiffs monetary damages through the individual agents of the EPA for their ultra vires actions, specifically the loss of payments on gross sales and royalty payments. Exh. A, B, D, & E. *See Id.*

B. Plaintiffs are highly likely to succeed on the merits.

7. In challenges to agency action, courts ask only “whether the [agency’s] decision was based on a consideration of the relevant factors” and “whether [the agency] has [made] a clear error in judgment.” *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971), abrogated on other grounds by *Califano v. Sanders*, 430 U.S. 99 (1977). Undoubtedly, the EPA has clearly erred in judgment when issuing SSUROs against entities which did not violate FIFRA. SSURO recipients and Plaintiff have made no pesticidal claims; they sell and distribute mechanical filters for treating water, the products are best seen as a treated article, and at most, a pesticidal device.

8. No rational person could conclude the recipients of the SSUROs, which were issued by the EPA based on a foreign website, were making pesticidal claims. Further, the statement from the foreign website claims the silver protects the filter, which is still not a pesticidal claim.¹ If the actual SSURO recipients were making pesticidal claims, the EPA’s SSUROs might have some basis, but as the SSUROs do not show such statements, and because silver is used to protect the filter elements and not present for pesticidal purposes, the SSUROs are without basis.

9. As Berkey filter elements are not pesticides, the SSUROs must be enjoined.

i. EPA ignores Berkey Filters mechanical process to destroy pests.

10. The court asks only “whether the [agency’s] decision was based on a consideration of the relevant factors” and “whether [the agency] has [made] a clear error in judgment.” *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971), abrogated on other grounds by

¹ See Exh. B6-11, SSUROs. (“Yes, silver is used as an antimicrobial to self-sterilize the Black Berkey® elements.”) (emphasis added)

Califano v. Sanders, 430 U.S. 99 (1977). Undoubtedly, the EPA has clearly erred in judgment when issuing SSUROs against persons who did not violate FIFRA by selling a pesticide under any definition, whether under the statutory definition of pesticide in FIFRA, 40 C.F.R. § 152, or plain English.

11. SSURO recipients and Plaintiff have made no pesticidal claims; they sell and distribute mechanical filters for treating water, the products are most reasonably seen as a treated article, or more tenuously as a pesticidal device as defined by the EPA. As the SSUROs were issued against entities not making pesticidal claims, the SSUROs should be enjoined.

- 1) **The EPA had no reason to believe the SSURO recipients or Plaintiff had sold any pesticide or device intended to be distributed or sold in violation of FIFRA or substances intended for preventing, destroying, repelling, or mitigating pest.**

12. The EPA has not shown that any SSURO recipient or Plaintiff intentionally sold or distributed any pesticide or device that violated FIFRA, nor have they shown the Berkey Products include substances intended for pesticidal purposes. All throughout EPA's answer it is clear that a pesticide includes a substance that *intends* to prevent, destroy, repel, or mitigate pests.

Since 1975, EPA has interpreted "devices" to include "water filters . . . (except those containing substances or mixtures of substances which are pesticides)." Part 162—Regulations for the Enforcement of the Federal Insecticide, Fungicide, and Rodenticide Act, 40 Fed. Reg. 28242, 28266 (July 3, 1975) (emphasis added). As EPA explained in a 1976 guidance document, if an "article incorporates a substance or mixture of substances intended to prevent, destroy, repeal, or mitigate any pest, it is considered to be a pesticide." Pest Control Devices and Device Producers, Consolidation and Clarification of Requirements, 41 Fed. Reg. 51065 (Nov. 19, 1976).

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EPA's longstanding view is reflected in more recent guidance available on the Agency's website. Under the heading "Products Commonly Mistaken as Devices," EPA notes that:

Where a product that would otherwise be a device also incorporates a pesticidal substance, it may be considered a pesticide product. For example, a filter that physically traps microbial pests (generally a device) would be an antimicrobial pesticide product if it also incorporated a pesticidal substance that kills those pests to improve the efficacy of the entire system.

U.S. EPA, Pesticide Devices: A Guide for Consumers, Pesticides, (last updated Dec. 29, 2022).³

The same website also explains that if a water filter "contains any substance intended to disinfect the water, then the unit is generally considered a pesticide that must be registered in order to be sold and distributed." *Id.*

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Similarly, EPA's Pesticide Registration Manual explains that if "a product consists of an object or article that incorporates a substance or mixture of substances intended to prevent, destroy, repel, or mitigate any pest, the entire product is considered to be a pesticide and is subject to registration under FIFRA section 3." U.S. EPA, *Pesticide Registration Manual: Chapter 13 - Devices*, Pesticide Registration, (last updated Mar. 1, 2023).⁴ The Pesticide Registration Manual

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13. The EPA is clearly in error because Berkey products are mechanical. To attempt to prove that Berkey Filters includes a pesticide intended to destroy pests, Defendants incorporate in their Appendix a post on the Berkey website with the heading "What does Berkey Water Filter Remove?" *See Defendant's Appendix*, pg. 1-39. Defendants marked the article with highlights attempting to show the pesticidal claim by Berkey, but Defendants only show the success of the mechanical filtration systems of Berkey Products. The article includes no mention of silver and explains in the introductory paragraph "Berkey Water Filter has *microfilaments* that can filter sediments and remove turbidity that is caused by chemicals and disease-causing microorganisms such as bacteria and viruses." Berkey only makes standard mechanical filter claims.

14. Further, EPA's article shows that Berkey Products use a mechanical filtration system. ECF 11, pg. 12. The EPA even highlights Berkey's claim of its device as "more powerful than any other gravity filter element currently available. The *micropores* within Berkey Filters (Black Berkey

Elements) are so small that viruses and pathogenic bacteria cannot pass through them.” (See Document 11 pg. 7). None of the claims on the Berkey post show silver as the reason for the mechanical devices’ filtration success.² Berkey products clearly show specific claims of mechanical filtering. The EPA cannot show otherwise. Further, Berkey *exceeds* NSF/ANSI Standards and even has a public posting of the report showing that the silver in the registered pesticide used to protect the filter does not leach into the effluent.

15. To the contrary, the EPA is in clear error because it has no reason to believe that SSURO recipients or Plaintiff “had sold products containing a ‘substance or mixture of substances *intended* for preventing, destroying, repelling, or mitigating, any pest.’” 7 U.S.C. §136(u).

2) No SSURO recipient made claims exceeding those allowed as a treated article.

16. The EPA expands its authority under 7 U.S. Code § 136k(a) by issuing SSUROs against recipients who have not distributed or sold any “pesticide or device . . . in violation of [FIFRA]” and have no “ownership, control, or custody of such pesticide or device.” The EPA quotes a foreign website making non-mechanical pesticidal claims that NONE of the SSURO recipients or Plaintiff made, published, or ratified. Further, the EPA issued the SSURO against recipients who have no control over the foreign party who made such claims or “such devices” under the control of the foreign party. The EPA has not shown the SSURO was limited to “such devices” directly arising from to the violation of FIFRA. Instead, the EPA is using an implausibly expansive reading of 7 U.S. Code § 136k(a) by wrongly issuing SSUROs against parties who have never made pesticidal claims in violation of FIFRA, nor sold or controlled any such devices originating from such violation. If the SSURO recipients or Plaintiff had actually made any pesticidal claims or sold or distributed devices or pesticides in violation of FIFRA, then perhaps the EPA would be justified.

² Clearly, Berkey Products are *mechanical*, not *electrical*, and do not employ electrodes to generate ions. See *Defendant’s Appendix*, Doc. 11, pg. 6-44.

17. Yet, the EPA chooses to punish law abiding persons stopping the sale of their devices while attempting to connect their devices to different foreign parties. Plaintiffs and SSURO recipients did not violate FIFRA or control any devices that were cited by the EPA in violation of FIFRA arising from the foreign claim.

4. EPA's enforcement authority

EPA "is charged with choosing the means by which to enforce and achieve the goals of FIFRA." *Sultan Chemists, Inc. v. EPA*, 281 F.3d 73, 83 (3d Cir. 2002). One enforcement option available to EPA is the issuance of a SSURO. 7 U.S.C. § 136k(a). EPA may issue SSUROs "[w]henever any pesticide or device is found by the Administrator in any State and there is reason to believe . . . that such pesticide or device has been or is intended to be distributed or sold in violation of any" provision of FIFRA. *Id.* Once issued, a SSURO prohibits the sale, use, removal

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18. The EPA has made no showing that the EPA had reason to know of any of the SSURO recipients or Plaintiff selling or distributing any pesticide "intended to be distributed or sold in violation of any provision of FIFRA." The EPA can only show some foreign website making statements about devices that SSURO recipients have no control over. Further, the evidence shown in Defendant's Appendix reiterates that Berkey Products official position is a very successful mechanical filter. No evidence presented by EPA can refute the actual showing by Plaintiff that Berkey has consistently maintained a public reputation for successful mechanical filtration systems. One must wonder why the EPA did not attach the easily available public post included in their Appendix to their SSUROs, but rather relied on the foreign website.

2. Stop Sale, Use and Removal Orders referenced in the Complaint

In 2022, due to a statement posted **on a website**, EPA became aware that Berkey water filtration system products contain silver being used for an antimicrobial purpose and that Plaintiffs' **manufacturers and distributors** claimed these products remove pests that threaten public health

from water. Compl. ¶ 57; Compl. Ex. B-2 at 5-7. Due to the silver in Berkey water filtration system products and the pest removal claims, EPA Regions 2, 4 and 8 began investigating the products to determine whether they required registration under FIFRA. Compl. Ex. B-2 at 5-7. EPA's investigation confirmed that Berkey water filtration system products contain silver; that Plaintiffs' manufacturers and distributors claim these products remove public health pests from water; that these products are not registered; and that Plaintiffs' distributors were selling these products throughout the United States. Compl. Ex. B-2 at 5-7. EPA therefore issued SSUROs pertaining to Regions 2, 4, and 8 in accordance with EPA's authority under FIFRA and EPA's FIFRA Enforcement Response Policy.¹⁰

Pg. 8 of Memorandum Highlights added)

19. EPA shows in this paragraph that neither SSURO recipients nor Plaintiffs made any pesticidal claims, but rather "a website" and Plaintiffs' alleged "manufacturers and distributors". Plaintiffs have stated that such websites were foreign and outside the control of Plaintiffs or SSURO recipients. Further, the statement by the foreign website relied on by the EPA clearly states that silver in the Berkey products is to protect the filter and not for a pesticidal purpose.

20. EPA is required to issue SSUROs on those persons who distributed or sold "such pesticide or device" in violation of FIFRA according to 7 U.S. Code § 136k(a). In the above paragraph, it is evident that the EPA cannot point to any SSURO recipient or Plaintiff that distributed a device with a pesticidal claim. The EPA relies on foreign nonparties that wrongly make pesticidal claims to wrongly issue SSUROs on law abiding companies within the US that distribute a registered treated article. Neither Plaintiff nor any SSURO recipient have claimed that the silver in the filter is to destroy or repel any pests, but to protect the filter only. The EPA's SSURO relies on statements that state as much. B-4, pg. 5 (alternate pg. num. Exhibit B pg. 17).

21. As shown above, none of the claims made by the SSURO recipients or Plaintiffs exceeded the claims allowed under the Treated Article Exemption. Berkey Products include a registered pesticide to protect the filter. See Exhibits A, D, E.

22. Even as shown in Defendant's exhibits, Plaintiff and Berkey Products consistently tout a mechanical filter with a substance intended to protect the filter, not for a pesticidal purpose. The Berkey Filters microfilaments and micropores are the cleansing mechanisms for the Berkey Products. The EPA cannot show any statement by any of the SSURO recipients or Plaintiff that exceeds any description of silver as protecting the filter. Berkey Products do not exceed the treated article exemption. SSURO recipients and Plaintiff make no non-mechanical pesticidal claims.

3) No SSURO recipient was required to register its products under 7 U.S.C. § 136a(a).

23. Incorporating the above paragraphs, Berkey Products are mechanical filters, as shown by the EPA and Plaintiff.³ The EPA has not stated any potential adverse effects from a mechanical filter that has been commercially sold for decades which also exceeds NSF/ANSI Standards. Further, no SSURO recipient or Plaintiff has made any pesticidal claim, nor have they distributed or sold any product subject to the SSUROs that includes a pesticide for a pesticidal purpose. As noted above, Berkey Products are treated articles that contain a registered pesticide *intended* to protect the filter. Exh. E. Again, there is no pesticide in the Berkey Products that is intended to mitigate pests. Berkey Products are treated articles. Berkey Products are not required to be registered under 7 U.S.C. § 136a(a).

ii. EPA violates the United States Constitution with arbitrary and capricious actions without notice and comment.

24. Plaintiffs wish to clarify that Plaintiffs rely on the Fifth Amendment and not the Fourteenth Amendment, which was incorrectly cited in the Original Complaint. Plaintiffs rely on the Fifth Amendment for EPA's violations of due process. Plaintiffs specifically refer to *Mathews v. Eldridge*, 424 U.S. 319, 333 (1976) on pg. 37 in reliance on the 5th Amendment. To ensure total clarity, Plaintiff has amended any alleged issue in their *First Amended Complaint*. The EPA

³ See above screen captures of Defendant's Answer; Defendant's Appendix; see Plaintiffs Original Complaint; Plaintiff's Amended Complaint.

violated Plaintiff's due process rights by not providing notice and an opportunity to be heard before the SSUROs were issued, causing injury to Plaintiffs through stopping gross sales of Berkey Products in the regular course of business.

iii. Plaintiffs remove individual capacity claims to focus on equitable relief.

25. Plaintiffs wish to clarify that while the EPA agents harmed Plaintiff by their *ultra vires* actions, the most important issue in this case is equitable relief for the SSURO recipients. Plaintiffs have filed their *First Amended Complaint* to reflect this.

iv. Defendant's actions have caused Plaintiff to suffer irreparable injury.

26. Plaintiffs' First Amended Complaint clarifies that Plaintiffs clearly have been harmed by Defendant's actions. Due to the license agreement for IP rights between Berkey International, LLC and JBS Trust, Berkey International, LLC is required to pay royalties of gross sales annually. Further, Berkey International, LLC and NMCL are required to pay royalties of all sales on products protected by the intellectual property to JBS Trust, per the individual licensing agreement between the Trust and Berkey, and the Trust and NMCL. Exh. E. Due to Defendant's SSUROs, sales have stopped and payments have been halted. Further, gross sales in the regular course of business cannot continue if sales are banned through SSUROs. The EPA has stopped Berkey International, LLC from selling Berkey Products and stopped the JBS Trust from receiving royalties.

v. A Stop Sale Order causes injury to Berkey product sales.

27. Plaintiffs are appalled that the EPA relies on a class action lawsuit that has not been decided on the merits, while completely ignoring the literal effect of a SSURO. Further, the EPA relies on hearsay articles that are completely false, Berkey is NOT banned in California but chose to not do business in California as a business decision.

28. The class action lawsuit cited by the EPA is in its beginning stages. *See 3:22-cv-728.* The merits have not been decided. The accused products have high ratings on Amazon, eBay, and other

commercial user rated cites. However, the EPA cannot argue against the literal effect of ordering a business to stop doing business and pay exorbitant fees for compliance. Further, the EPA only continues to attempt to harm Berkey by offering false hearsay in this case.

29. The purpose of SSUROs is to stop business. 7 U.S. Code § 136k. The statute shows that a SSURO will literally stop business sales: “after receipt of such order no person shall sell, use, or remove the pesticide or device described in the order except in accordance with the provisions of the order.” The literal effect of the SSURO is to order a business to stop selling. A business that is not selling its goods in the regular course of business cannot fulfill the demands of their consumers, resulting in lost business and market share. A business that cannot sell goods cannot make sales. No typical business has ever improved or maintained its position in the regular course of business by ceasing to do business. Obviously, the EPA has damaged the Plaintiffs. Lawsuits come and go, but a SSURO ends business.

30. Plaintiffs chose not to do business in California due to the regulatory burden of selling their larger Berkey systems in California. California has not issued any order banning Berkey Products.⁴ The EPA chose to handpick an unfavorable hearsay article rather than simply look into Berkey’s public explanation. In addition, even if the article cited were a credible source of facts, being banned in California does not confer the designation of “pesticide” on a product.

I. PRAYER

For all of the reasons stated above, the EPA wrongly issued SSUROs against the SSURO recipients, resulting in harm to Plaintiffs. Berkey products are successful mechanical filters. Plaintiffs incorporate their *First Amended Complaint* in light of *Defendant’s Memorandum* and this Reply. Additionally, the separately filed Declaration of James “Jim” B. Shepherd Regarding Trade Secrets should be considered, with its additional details.

⁴ <https://theberkey.com/pages/why-some-berkey-products-are-not-available-in-california>

Respectfully submitted,

/s/Warren V. Norred
Warren V. Norred
Norred Law, PLLC
Texas Bar Number: 24045094
warren@norredlaw.com
515 E. Border St.
Arlington, TX 76010
(817) 704-3984 (Office)
(817) 524-6686 (Fax)
Counsel for Plaintiffs

CERTIFICATE OF SERVICE

I certify that on Thursday, August 24, 2023, I filed this reply with the Clerk of the Court through the ECF system, which will send notification of such filing to the following by email to Andrew Coghlan, Shari Howard, and Mark Walters, at the addresses shown below:

TODD KIM
Assistant Attorney General Environment & Natural Resources Division
Andrew Coghlan (CA Bar. No. 313332)
Shari Howard (IL Bar No. 6289779)
Mark Walters (TX Bar No. 00788611)
United States Department of Justice
Environment & Natural Resources Division
Environmental Defense Section
P.O. Box 7611; Washington, D.C. 20002
Tel: (202) 598-9407
Fax: (202) 514-8865
andrew.coghlan@usdoj.gov
shari.howard@usdoj.gov
mark.walters@usdoj.gov
Attorneys for Federal Defendants

I will send this document to the individual defendants through their email:
Christine Tokarz, FIFRA Inspector, EPA, Region 8, tokarz.christine@epa.gov
David Cobb, Section Supervisor, Region 8, cobb.david@epa.gov
Carol Kemker, Region 4, kemker.carol@epa.gov
Keriema Newman, newman.keriema@epa.gov

/s/*Warren V. Norred*
Warren V. Norred